UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
	Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO: ALL CLASS ACTIONS	Judge Patti B. Saris

REPLY MEMORANDUM IN SUPPORT OF SCHERING-PLOUGH CORPORATION'S AND WARRICK PHARMACEUTICALS CORPORATION'S MOTION FOR SUMMARY JUDGMENT AS TO CLASS 2 CLAIMS

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Schering-Plough Corporation ("Schering") and Warrick Pharmaceuticals Corporation ("Warrick") respectfully submit this reply memorandum in support of their motion for summary judgment as to Class 2 claims ("Schering's and Warrick's Motion").

INTRODUCTION

Theory, hyperbole and speculation are not sufficient to avoid summary judgment, and that is all that the Plaintiffs proffer in opposition to Schering's and Warrick's Motion. Plaintiffs concede the essential facts supporting the motion: Warrick had no incentive, and virtually no ability, to manipulate the median-based reimbursement rate used by Medicare for albuterol, and neither Schering nor Warrick changed AWPs for albuterol for any reason since 1995. The vigorous price competition in the self-administered market, the existence and benefits of which were established during the class-certification stage of this action, fully affects the pricing of albuterol, which is self-administered and dispensed by pharmacies.[1]

Faced with the indisputable record that Schering and Warrick engaged in no more than vigorous price competition in a market characterized by vigorous price competition, Plaintiffs have fundamentally changed their theory of the case. After more than four years of arguing that generic and multi-source manufacturers were playing a hotly contested game of "leap frog" with their competitors, in which each manufacturer would try to take market share from competitors by raising its AWP over theirs, Plaintiffs (through Dr. Hartman) now assert that these same manufacturers were colluding with one another to inflate the median AWP to take market share from unidentified manufacturers of unidentified "therapeutic alternatives." This new theory has

[1] The pending motion brings into sharp focus the exceptional – and perhaps unintended – intersection of two of Plaintiffs' proposed classes: the self-administered drug class, which the Court declined to certify for a number of reasons, including the competitive nature of the market, and the Medicare Part B class, which the Court certified in the apparent belief that it addressed only physician-administered drugs. As we demonstrate below, self-administered pharmacy-dispensed drugs such as albuterol simply do not fit within the theories presented by Plaintiffs in seeking class certification.

been proffered without support in the factual record, in relevant economic theory, in medical science, or in common sense. And it is diametrically opposed to this Court's recognition of a pharmacy market replete with vigorous price competition—the very sort of competition, encouraged by law, that was a fundamental element of this Court's refusal to certify a class of self-administered drugs.

Plaintiffs' new theory proves too much: No generic or multi-source manufacturer could escape liability. Having chosen to participate in the marketplace, they become liable for enormous damages merely because price competition increases spreads between typically static AWPs and falling market prices. So-called "mega spreads" inevitably arise, precisely because the market is vigorously competitive on price, as the government was well aware. Thus, even though "mega spreads" are the result of the very price competition that the government encouraged through the Hatch-Waxman Act and other legislation, and the government was well aware of the "mega spreads" that ensued, still – under Plaintiffs' current theory – universal liability exists. This theory is flatly inconsistent with Plaintiffs' prior assertion the AWP system "works" for the vast majority of pharmaceutical manufacturers and their products,[2] and it is contrary to the elemental notion that a company can avoid liability for fraud, or for unfair or deceptive practices, by conforming its behavior to widespread industry norms.

Apart from changing their theory of the case to sidestep summary judgment, Plaintiffs offer nothing substantive in opposition to the pending motion. Accordingly, summary judgment for Schering and Warrick should be entered.[3]

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[2] Written Tutorial of Meredith Rosenthal, Ph.D. (Dec. 9, 2004) (Docket No. 1222) at 3 n.2.

[3] Schering and Warrick also adopt and incorporate herein the arguments contained in the Reply Memorandum of Law in Further Support of Track 1 Defendants Joint Motion for Summary Judgment.

ARGUMENT

I. PLAINTIFFS' NEW THEORY OF LIABILITY FOR GENERICS IS NOT SUPPORTED BY EVIDENCE, ECONOMIC THEORY, OR COMMON SENSE

Plaintiffs have stated repeatedly throughout this litigation that the alleged AWP scheme arose out of cut-throat competition, each manufacturer inflating AWP to take market share from others. (*See, e.g.*, Fourth Am. Master Consolidated Class Action Compl. ("FAMCC") ¶ 197-200.) Indeed, the Court has already had occasion to rule that "the key allegation in the [complaint] is that pharmaceutical companies compete (*not conspire*) with one another for market share by boosting the AWP . . . ." *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 94 (D. Mass. 2005) (emphasis added). Moreover, a key basis for the Court's decision to certify Class 2 was its observation that Plaintiffs had abandoned their conspiracy claims and "are pressing only the theory that defendants intentionally made fraudulent misrepresentations of AWP." *Id.* at 88.

In their brief supporting summary judgment, Schering and Warrick explained that a manufacturer has no incentive to manipulate a median-based reimbursement rate because a change would be uniform for all manufacturers, thus providing no competitive advantage; that the ability of any manufacturer to change a median unilaterally is very limited, as basic mathematics dictates; and that there is in any event no evidence of any change in Warrick or Schering AWPs that could have affected the median. (Schering's and Warrick's Mem. Supp. Summ J. at 14-16.) It was no doubt for reasons such as these that the Court has already ruled that median-based[4] ("MAC") reimbursement in the private context is not part of the class. 230 F.R.D. at 96.

[4] As the Court stated, a MAC price "is often based on the median or mean of the AWPs of several different manufacturers' versions of a drug." 230 F.R.D. at 74.

When confronted with an indisputable refutation of their theory as applied to generic and multi-source drugs reimbursed on a median AWP, Plaintiffs now allege that there is collusion where once they had described competition. Under this new paradigm, generic manufacturers worked "to increase the spreads of all manufacturers relative to potential alternative therapeutic competitors," so as to take market share from these unidentified alternative therapeutic competitors.[5] (Decl. of Raymond S. Hartman Opp'n Defs.' Mots. Summ. J. ("4/7/2006 Hartman Decl.") ¶ 21(d)).

This new theory proceeds as if Plaintiffs had never argued that generic competitors try to take market share from one another. Yet, Dr. Hartman does not provide a stitch of evidentiary support for this startling assertion and offers no explanation for its appearance out of the blue. Nor does he define or present evidence of who or what these so-called "alternative therapeutic competitors" are. Depending upon what a therapeutic alternative to a generic might be, the very same entities that are now alleged to be collaborating with one another to raise median AWPs might be the targets of that effort by virtue of their manufacture of some other product. Of course, the ultimate irony – and refutation – of Plaintiffs' new argument is that generic competition is the ultimate stage in the evolution of therapeutic competition for a particular drug. Indeed, this Court has observed, in the multi-source arena, as a result of competition for pharmacy business, "[t]he pharmacy is in the driver's seat" rather than the generic manufacturer,

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[5] Plaintiffs should not be permitted to present a new theory of their case at this late stage in the litigation. "It is well-settled that plaintiffs are generally not permitted to raise brand new theories of their case in opposition to a motion for summary judgment, particularly where, as here, they have been given ample latitude to amend their complaint." *Agri-Mark, Inc. v. Niro, Inc.*, 233 F. Supp. 2d 200, 207 (D. Mass. 2002) (citing *Briddle v. Scott*, 63 F.3d 364, 380 (5th Cir. 1995); *Murphy v. White Hen Pantry Co.*, 691 F.2d 350, 353 (7th Cir. 1982); *Deghand v. Wal-Mart Stores, Inc.*, 926 F. Supp. 1002, 1015 (D. Kan. 1996); *Mortkowitz v. Texaco, Inc.*, 842 F. Supp. 1232, 1236 (N.D. Cal. 1994)). "Allowing addition of a new theory of liability after the defendant's . . . motion for summary judgment and after discovery had closed . . . unquestionably would prejudice defendant . . . ." *Torres-Rios v. LPS Labs., Inc.*, 152 F.3d 11, 16 (1st Cir. 1998) (affirming grant of defendant's motion for summary judgment and denial of plaintiffs' motion to amend in products liability case).

and "[p]harmacies play a greater role in determining the spread for generic self-administered drugs than for brand-name drugs . . . ." 230 F.R.D. at 74.

More fundamentally, Plaintiffs are *incapable* of providing any support for their new – and purely speculative – claim. By failing to identify so much as a single "potential alternative therapeutic competitor," Plaintiffs do not – and cannot – provide even one example supporting their claim. Such a claim might be sufficient to withstand a motion to dismiss or to support a motion for class certification, but it cannot suffice in response to a motion for summary judgment.[6]

As an additional theory, Plaintiffs also assert that Schering and Warrick affected the reimbursement rate for albuterol because Warrick established its AWP at 10-20% below Schering's Proventil and all of the other generic manufacturers followed Warrick in a "tacit Nash equilibrium."[7] (4/7/2006 Hartman Decl. ¶ 21(d).) Dr. Hartman's new pronouncement, which is a red herring cloaked in economic jargon, is not accompanied by any analysis or other support. (Supplemental Declaration of Sumanth Addanki, Ph.D. ("4/28/2006 Addanki Decl.") ¶ 27.) Indeed, he completely ignores the fact that multiple other branded versions of albuterol also existed in the market. (4/28/2006 Addanki Decl. ¶ 33.) Which of these, if any, "set" the market is left entirely to speculation. In addition, Dr. Hartman does not explain why Schering would or should have lowered its AWP when as late as 1999 more than 60% of its sales were occurring at,

[6] It is worth noting as well that Plaintiffs and Dr. Hartman represented to the Court that, when the time came to address Plaintiffs' arguments (and Dr. Hartman's supporting opinions) on the merits, they would be supported by surveys that developed a factual record regarding the knowledge and expectations of third-party payers. *See* 230 F.R.D. at 87-88, 93 (discussing Dr. Hartman's "survey" methodology). Dr. Hartman never conducted any such surveys, and all of his "opinions" on these subjects are based entirely on his say-so.

[7] This phrase describes a condition without regard to its cause or effects. (4/28/2006 Addanki Decl. ¶ 27.) Use of this useless jargon follows a familiar pattern in Plaintiffs' papers. In any event, economic theory indicates that tacit collusion is most likely *not* the proper explanation for the observed behavior because the economic foundations for collusion are not present. (4/28/2006 Addanki Decl. ¶¶ 28-31.)

or within 2%, of list price. (4/28/2006 Addanki Decl. ¶ 32.) Again, Plaintiffs' new theory is entirely unsupported.

Plaintiffs' new – and entirely implausible – theory is contrary to antitrust law and the evidentiary record. Plaintiffs' new approach attempts to recast normal price competition, which abounds in the generic marketplace, as collusive and unlawful. The Supreme Court has stated, however, that price competition is not only lawful, but that it must be protected in the courts:

> [C]utting prices in order to increase business often is the very essence of competition. Thus, mistaken inferences in cases such as this one are especially costly, because they chill the very conduct the antitrust laws are designed to protect. "[We] must be concerned lest a rule or precedent that authorizes a search for a particular type of undesirable pricing behavior end up by discouraging legitimate price competition."

Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 594 (1986) (citations omitted). Ironically, imposing Plaintiffs' legal regime would require manufacturers to collude: If manufacturers were required to report AWPs that reflect the actual prices at which providers (physicians and pharmacies) purchase those drugs, they would necessarily have to investigate those prices (now largely unknown to them where sales are to wholesalers), to report the results of that investigation, and then to enforce the prices they report (*i.e.*, the prices that providers pay). Plainly, such conduct would amount to vertical price fixing or resale price maintenance violative of the antitrust laws.[8] *See, e.g., Dr. Miles Medical Co. v. John D. Park & Sons Co.*, 220 U.S. 373 (1911); *United States v. Colgate & Co.*, 250 U.S. 300 (1919).

Plaintiffs' new theory is even more implausible than their old one, and a theory that implausible cannot survive summary judgment without unusually persuasive evidence. *Matsushita*, 475 U.S. at 587 (holding that "if the factual context renders respondents' claim

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[8] Moreover, as this Court noted in its class certification opinion, some argue that forcing disclosure of acquisition prices would reduce competition and would be "'likely to increase rather than decrease consumers' prices'." 230 F.R.D. at 93 (quoting 2/9/2005 Report of Independent Expert Prof. Ernst R. Berndt (Docket No. 1384) ("Berndt Report") ¶ 16).

implausible – if the claim is one that simply makes no economic sense – respondents must come forward with more persuasive evidence to support their claim than would otherwise be necessary"). Plaintiffs' evidence is not only unpersuasive, it is entirely lacking in several critical respects:

- They present no evidence of collusion among albuterol (or any other) manufacturers;
- They do not identify a single purported "alternative therapeutic competitor" with which the group of albuterol (or any other) manufacturers were allegedly competing;
- Because they fail to identify any "alternative therapeutic competitor," they are incapable of showing that albuterol spreads are greater than those of any such competitor, as is now alleged;
- They admit that Warrick had no incentive to inflate its AWPs and in fact did not change AWPs since 1995;[9]
- Their assertion that Schering determined the median AWP by inflating Proventil's AWP is directly contrary to the evidentiary record showing that other branded albuterols existed, and 60% of Proventil sales were within 2% of list price.[10]

Simply put, Plaintiffs' new theory is ultimately nothing more than an unsustainable indictment of the entire generic industry—the very segment of the industry that unarguably presents the strongest indicia of price competition and, through lower prices, unquestionably benefits consumers. Plaintiffs' complaint, at its essence, is that Warrick did not adjust its AWPs to correspond with market prices. But Plaintiffs admit that all manufacturers almost never adjust their AWPs for multi-source drugs. (4/7/2006 Hartman Decl. ¶ 21(d).) Not only would every manufacturer in the generic and multi-source industry be liable under this fanciful legal regime, but in order to escape liability generic manufacturers would have to engage in behavior that is

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[9] (4/7/2006 Hartman Decl. ¶ 21(d).)

[10] (4/28/2006 Addanki Decl. ¶ 32.)

anticompetitive on its face.[11] (Schering's and Warrick's Mem. Supp. Mot. Summ. J. at 8.) Such a theory of liability is pernicious.

II. PLAINTIFFS' "EVIDENCE" OF MARKETING AND MANIPULATING SPREADS IS NOT INDICATIVE OF THOSE BEHAVIORS

As Schering and Warrick explain in their Opposition to Plaintiffs' Motion for Summary Judgment Against All Track 1 Defendants, the scant few documents that Plaintiffs proffer as evidence of manipulating or marketing the spread are not indicative of any such thing. (*See* Schering's and Warrick's Mem. Opp'n Summ J. at 7-9.) With respect to the few facts Plaintiffs attempt to contest,[12] Plaintiffs blatantly take testimony and information out of context, draw unsupported inferences, and rely on conclusory assertions. (*Id*.) The remainder of the "evidence" that Plaintiffs proffer against Schering and Warrick amounts to nothing more than documents demonstrating that Schering and Warrick competed on price. None of this is evidence that Schering or Warrick manipulated or marketed the spread.[13] (*Id.* at 11.)

Plaintiffs' assertion that Schering and Warrick did not move for summary judgment as to drugs other than Proventil and albuterol is incorrect. Schering and Warrick did move for summary judgment as to all of the Part B drugs at issue and used albtuerol and Proventil – which account for more than 90% of the alleged damages – to establish principles that apply *mutatis*

[11] Singling out Schering and Warrick is entirely arbitrary, as it is undisputed that no one manufacturer could change industry practice unilaterally without committing economic suicide. (Berndt Report ¶ 29.) As a matter of law, this cannot be the basis for a violation of Chapter 93A § 11, which assigns liability only for conduct that violates "the standard of the commercial marketplace."

[12] Strikingly, Plaintiffs admit the vast majority of the facts identified in Schering's and Warrick's 56.1 Statement. With respect to those few facts that Plaintiffs try to contest, their responses fail to create any genuine issue as to any material fact. (*See* Summ. of Pls.' Resp. to Schering's and Warrick's 56.1 Stmt., attached hereto as Ex. A.)

[13] Plaintiffs' arguments about the relationship between Schering and Warrick are wrong and irrelevant. They are wrong because their evidence falls woefully short of what is required to pierce the corporate veil. *See, e.g., Platten v. HG Bermuda Exempted Ltd.*, 437 F.3d 118, 127-8 (1st Cir. 2006). The Plaintiffs' arguments are irrelevant because they have no bearing on any of the arguments adduced by Warrick and Schering in relation to median-based reimbursement or any other subject.

mutandis to the others. Plaintiffs claim no damages with respect to Integrilin, nor can they. Perphenazine was subject to negligible reimbursement under Part B, but in any event is also reimbursed based on a median.[14] (3/15/2006 Addanki Decl. ¶ 16 n.2.) Plaintiffs otherwise can present no evidence that Schering or Warrick manipulated the spreads for any of their drugs. Thus, the Court should grant Schering's and Warrick's motion in its entirety.

III. THE CAUSES AND CONSEQUENCES OF "MEGA SPREADS" ARE BENIGN

The principal cause of large spreads in the generic market is a divergence of two independent economic forces. One force tends toward static AWPs: Generic manufacturers tend to benchmark AWPs to branded competitors as they enter the marketplace. The second is price competition, which drives prices down. The difference between a static AWP and a falling price is an increasing spread. Sharply falling prices, such as occur in the generic market, cause "mega spreads."

Plaintiffs are particularly fond of focusing on spreads of 1000% or more. Yet, it is undisputed that the largest spreads tend to occur where the products at issue are priced in pennies. The lower the cost of a drug, the larger the percentage spread caused by a dollar discount. A dollar discount on a drug with an AWP of $10 creates a spread of about 10%, but a discount of a dollar on a drug with an AWP of $1.10 produces a spread of about 1000%.[15]

There is no dispute that the government frequently surveyed pharmacists to determine acquisition costs and conveyed the resulting information to CMS, which was responsible for

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[14] The only evidence that Plaintiffs present as to perphenazine was that spreads existed between its AWP and market prices. (Pls. Mem. Opp'n Schering's and Warrick's Mot. Summ. J. at 16).

[15] For example, a 2002 OIG report on albuterol shows acquisition costs as low as $0.05 and Medicare reimbursement of $0.47. Forty-two cents translates into a "spread", as calculated by Dr. Hartman, of 843%. HHS-OIG, *Excessive Medicare Reimbursement for Albuterol* (March 2002) at 17, attached as Ex. 21 to Decl. of Eric P. Christofferson Transmitting Docs. Relied upon in Schering-Plough Corp.'s and Warrick Pharmaceuticals Corp.'s Mot. for Summ J.

Medicare reimbursement rates. (*See, e.g.*, Defs.' Mem. Supp. Summ. J. at 21 n.53) Fully six OIG reports informed CMS during the class period of spreads on albuterol alone (Schering and Warrick's 56.1 Stmt. ¶¶ 67-72), which were among the highest spreads reported in any OIG reports and were for that reason – if for no other – certain to earn the attention of CMS, as even the Plaintiffs' expert concedes. (*See* 4/7/2006 Hartman Decl. ¶ 11(f).) Possessed of this knowledge of mega spreads, CMS maintained Medicare reimbursement rates far in excess of acquisition costs for two reasons that the agency articulated and the Plaintiffs cannot dispute: To encourage the use of lower-cost generics[16] (the lower cost itself contributing to seemingly larger spreads in percentage terms because the pennies involved were fewer), and to subsidize inadequate dispensing fees for pharmacies and administration fees for physicians.[17] The root cause of mega spreads is thus benign and their existence well known to the government. Schering and Warrick were nothing more than participants in the reimbursement system designed by the government, understood by the government, and used by the government for its own policy objectives. There can be nothing culpable in that.

CONCLUSION

For all of the foregoing reasons, and those contained in their and the Track 1 original memoranda and the memoranda in opposition to Plaintiffs' motion, Schering and Warrick respectfully request that their motion be GRANTED.

[16] As the Court noted in the context of the private payor market: "Because a TPP typically saves substantial money by paying for generics instead of brand-names, 'the third party payor is less likely to quibble over whether the pharmacy is pocketing a larger margin for generics than for brands'." 230 F.R.D. at 75 (quoting Berndt Report ¶ 52).

[17] (*See* Defs.' 56.1 Stmt. ¶¶ 79, 81, 82 (quoting testimony of then-HCFA Administrator Thomas Scully regarding need to cross-subsidize for some services); *see also* Defs.' 56.1 Stmt. ¶¶ 68, 70, 76, 84, 87, 90-92 (reflecting governmental consideration of need to increase payment for physician drug administration services).)

Respectfully submitted,

SCHERING-PLOUGH CORPORATION AND
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Dated: April 28, 2006

CERTIFICATE OF SERVICE

I hereby certify that on April 28, 2006, I caused a true and correct copy of the foregoing to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

/s/ Eric P. Christofferson______
Eric P. Christofferson